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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,721	05/29/2002	Radhakrishna K. Pillai	003102-00092	3156
35743	7590	08/06/2004	EXAMINER	
KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 919 THIRD AVENUE NEW YORK, NY 10022			TUCKER, PHILIP C	
			ART UNIT	PAPER NUMBER
			1712	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/042,721	Applicant(s) PILLAI ET AL.	
	Examiner Philip C Tucker	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,11,12,39,51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,11,12 and 39 is/are rejected.
- 7) ☒ Claim(s) 50 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 11 is objected to because of the following informalities: Claim 11 teaches that m' may be zero, which has the same meaning as A1 is a single bond, as previously cited in the claim. Appropriate correction is required.

Double Patenting

2. Applicant is advised that should claim 6 be found allowable, claim 11 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 6, 11, 12 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. These claims teach that m may be zero, thus creating a direct single bond from the tertaaza-cyclododecane ring to the carbonyl group of the side chain. Such was not supported by the specification as originally filed, and is new matter. Dependent claims fall herewith.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 6, 11, 12 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Society of Magnetic Resonance in Medicine, Book of Abstracts, 8th Annual Meeting, August 12-18, 1989.

Society of Magnetic Resonance teaches the biodistribution of Gd complex PA-DO3A in mice as a function of lipophilicity. Society of Magnetic Resonance differs from the selected species of the present invention in that an alkyl group (propyl or butyl), or 2 alkyl groups comprising 3 carbon atoms (methyl + ethyl), are replaced by hydrogen atoms. As homologues with such similar structures would be expected to have similar properties and utility, it would be obvious to one of ordinary skill in the art to make various homologues of PA-DO3A, including the methyl, propyl or (methyl + ethyl) substituted compounds of the present invention, for use in the study of lipophilicity in

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mice. It is noted that claims 6 and 11 encompass the methyl homologue, since the requirement for the combination of R1 and R2 to have at least 3 carbon atoms does not appear. There is clear basis in the case law for rejections of obviousness based upon homology in which an alkyl group or more than one alkyl group is substituted for hydrogen in a known molecule (Ex parte Fague 121 USPQ 425). See also In re Wood 199 USPQ 137 and In re Hoch 166 USPQ 406, cited by the Boards of Appeals in parent application 08/471556.

7. Claims 51 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Applicants arguments and amendment have been considered but are not deemed fully persuasive. The limitation of "or a single bond" was not deleted from claim 11, thus the objection is maintained.

In considering the structures 3-12 on page 39, it is clear that m is not zero, since there is clearly a CH₂ group between the ring and the carbonyl, since the linking group is not shown as a straight line, but possesses a bend, indicating the presence of a CH₂ group. The rejection under 35 USC 112 is thus maintained.

Contrary to applicants arguments, the addition of more than one CH₂ group to the PA-DO3A compound of the prior art produces the homologues of the present invention (see Ex parte Fague, supra). Hindsight cannot be involved when case law

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has stated that such is obvious. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant has only demonstrated superior results for compounds with much more complex substituents than the alkyl groups which are encompassed by applicants claims. In trying to establish superior and unexpected results, the test data must be commensurate in scope with the claims in question (*In re Kerkhoven* 205 USPQ 1069). None of the results discussed by applicant in the response apply to the alkyl substituted compounds, but to other substituents. Applicant has thus not established superior and unexpected results which are commensurate in scope with the claim, inclusive of the alkyl groups and selected species.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip C Tucker whose telephone number is 571-272-1095. The examiner can normally be reached on Monday - Friday, Flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Philip C Tucker
Primary Examiner
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